



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,951	02/04/2002	Keith Biggadike	PG4734	6056

23347 7590 10/03/2003

DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY
GLAXOSMITHKLINE
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 10/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,951

Applicant(s)

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 and 6-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 4 and 6-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Non-Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

2. The provisional rejection of claims 1, 2 and 5 under the judicially created doctrine of obviousness-type double patenting over claims 13 and 15-27 of copending Application No. 09/958,050 is made moot by the cancellation of the instant claims.

3. The provisional rejection of claims 4 and 6-15 under the judicially created doctrine of obviousness-type double patenting over claims 13 and 15-27 of copending Application No. 09/958,050 is withdrawn.

4. The provisional rejection of claims 1, 2 and 5 under the judicially created doctrine of obviousness-type double patenting over claims 1-19 of copending Application No. 10/066,964 is made moot by the cancellation of the instant claims.

5. The provisional rejection of claims 4 and 6-15 under the judicially created doctrine of obviousness-type double patenting over claims 1-19 of copending Application No. 10/066,964 is withdrawn.

Art Unit: 1616

6. The provisional rejection of claims 1, 2 and 5 under the judicially created doctrine of obviousness-type double patenting over claims 1-18 of copending Application No. 10/066,836 is made moot by the cancellation of the instant claims.

7. The provisional rejection of claims 4 and 6-15 under the judicially created doctrine of obviousness-type double patenting over claims 1-18 of copending Application No. 10/066,836 is withdrawn.

8. The provisional rejection of claims 1, 2 and 5 under the judicially created doctrine of obviousness-type double patenting over claims 1-25 of copending Application No. 10/067,020 is made moot by the cancellation of the instant claims.

9. The provisional rejection of claims 4 and 6-15 under the judicially created doctrine of obviousness-type double patenting over claims 1-25 of copending Application No. 10/067,020 is withdrawn.

10. Claims 4 and 6-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/241,658. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α -(2-furanylcabanoyloxy) ester of fluticasone. The latter application differs from the present application by the recitation of a crystalline

Art Unit: 1616

form of the claimed compound. However, (a) the compositions of the instant application encompass all forms of the claimed compound including crystalline forms thereof (see page 17, line 10 – page 18, line 14 of the present application) and (b) the compositions of the latter application encompass aqueous formulation comprising the claimed compound (see section 0057 of the latter application). Thus, the claimed composition of the latter application is encompassed by the instantly claimed composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 15, 18 and 21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 8-14 of copending Application No. 10/281,735. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to a method of treating an inflammatory condition by administration of a composition comprising the 17α -(2-furanylcabanoyloxy) ester of fluticasone. The latter application, unlike the present application, is limited to treatment of COPD utilizing the claimed compound and a long-acting β_2 -adrenoreceptor agonist. However, (a) the compositions utilized by the present application comprises the utilization of long-acting β_2 -adrenoreceptor agonists for treatment of inflammatory conditions such as COPD (see page 11, lines 24-30; page 12, lines 23-26; page 15, lines 13-27 of the present application) and (b) the composition of the latter application may be administered as an aqueous formulation (see sections 0071, 0073, 0074 and 0081 of the latter application).

Thus, the claimed composition of the latter application is encompassed by the instantly claimed composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 4 and 6-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/067,010. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α -(2-furanylcarbanoyloxy) ester of fluticasone. The latter application differs from the present application by the recitation of a crystalline form of the claimed compound. However, (a) the compositions of the instant application encompass all forms of the claimed compound including crystalline forms thereof (see page 17, line 10 – page 18, line 14 of the present application) and (b) the compositions of the latter application encompass aqueous formulation comprising the claimed compound (see section 0069 of the latter application). Thus, the claimed composition of the latter application is encompassed by the instantly claimed composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 4 and 6-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of

Art Unit: 1616

copending Application No. 10/200,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α -(2-furanylcarbanoyloxy) ester of fluticasone. The latter application differs from the present application by the recitation of a crystalline form of the claimed compound. However, (a) the compositions of the instant application encompass all forms of the claimed compound including crystalline forms thereof (see page 17, line 10 – page 18, line 14 of the present application) and (b) the compositions of the latter application encompass aqueous formulation comprising the claimed compound (see section 0058 of the latter application). Thus, the claimed composition of the latter application is encompassed by the instantly claimed composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 4, 7, 10 and 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because it (a) does not end with a period and (b) contains a period in the middle of the claim (see page 3, line 1 after the structure). Thus, the

skilled artisan would be unable to determine the metes and bound of the claimed invention.

Claim Rejections - 35 USC § 102

16. The rejection of claims 1-3 and 5 under 35 USC 102(b) over Sjoquist (WO 99/32089) is made moot by the cancellation of the instant claims.

17. The rejection of claims 9, 11 and 13-15 under 35 USC 102(b) over Sjoquist (WO 99/32089) is withdrawn.

Claim Rejections - 35 USC § 103

18. The rejection of claims 4, 6-8, 10 and 12 under 35 USC 103(a) over Sjoquist (WO 99/32089) in view of Adjei et al. ('294) and/or Straub et al. ('300) is withdrawn.

19. Claims 6, 8, 9, 11 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sjoquist (WO 99/32089) in view of Ziegler et al. ('246).

Sjoquist teaches a stable formulation of glucocorticosteroid/glucocorticosteroid ester comprising a surfactant for use in treating allergic and/or inflammatory diseases (see the entire article; especially page 2, lines 18-21; page 3, lines 3-11, 16-27; page 5, lines 7-10, line 17 – page 6, line 5; page 8, lines 1-28; page 9, lines 4-18). The reference teaches (a) glucocorticosteroid ester such as fluticasone propionate (see page 6, line 20-22; page 11, claim 7); (b) surfactants such as poloxamer,

Art Unit: 1616

polyoxyethylene sorbitan fatty acid esters and polyoxyethyleneglycol hydroxystearates (see page 5, line 24 – page 6, line 5); (c) the addition of one or more acceptable additives such as modifying agents such as glucose (see page 7, lines 18-29; page 12, claim 11) and (c) administration by oral or nasal inhalation in pressurized metered dose inhalers (see page 1, lines 20-29; page 9, lines 5-8).

The instant claims differ from the reference by reciting a limited number of surfactants. However, Sjoquist teaches, "by dissolving the lipophilic glucocorticosteroid in a surfactant, preferably a **non-ionic surfactant**, stable compositions can be obtained with the glucocorticosteroid in micellar form" (see page 5, lines 7-10). Sjoquist teaches non-ionic surfactants such as polyoxyethylene sorbitan fatty acid esters and polyoxyethyleneglycol hydroxystearates but does not exemplify the specific non-ionic surfactants recited by the instant claims. However, the surfactants recited by the instant claims are known non-ionic surfactants as shown by Ziegler et al. (see col. 6, lines 31-37). Ziegler teaches non-ionic surfactants such as polyethylene glycol, octylphenoxypolyethoxyethanol and fatty acid esters of polyoxyethylene sorbitan. Thus, it would be obvious to one skilled in the art at the time of the invention to make the compositions taught by Sjoquist utilizing fluticasone propionate and a non-ionic surfactant such as octylphenoxypolyethoxyethanol with the reasonable expectation of obtaining a stabilized composition useful in treatment of allergic and/or inflammatory diseases as taught by Sjoquist.

Respons to Arguments

20. Applicant argues in regards to claims 9, 11 and 19-21 that he was unable to identify in Sjoquist any disclosure of hydroxy containing organic co-solvating agent or phosphatidyl choline or the use of dextrose for any purpose.

First, it is noted that glucose and dextrose refer to the same compound and that Sjoquist teaches the use of glucose (and thus dextrose) in adjusting the isotonicity of the formulation. Applicant also argues that glucose is not taught as a co-solvating agent as recited by the claimed invention. The examiner notes, that recitation of the intended use of the glucose does not lend patentability to the claimed invention because one cannot separate a compound from its various properties. Thus, glucose (dextrose) incorporated in the prior art composition would have similar properties as in the claimed composition especially when the compositions comprise similar components.

Applicant also argues the reference does not teach the use of a hydroxy containing organic co-solvating agent. The examiner notes that there are several hydroxy containing organic agents taught by Sjoquist. For example, glucose, mannitol, glycol and surfactants such as polyoxyethylene alkyl ethers, polyoxyethleneglycol hydroxystearates etc. (see page 5, line 24 – page 6, line 5; page 7, lines 23-29). Again, the examiner notes that a compound and its various properties cannot be separated. Thus, the recitation in the claimed invention of applicant's intended use of the compounds does not lend patentability to the claimed composition.

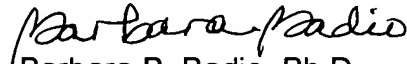
Art Unit: 1616

Telephone Inquiry

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
September 29, 2003